K012676

Adven Medical, Inc.

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Lubbock, Texas 79404

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FEB 0 4 2002

510(k) SUMMARY

Re: Adven Medical, Inc. 510(K) Notification:
Reprocessed Used Disposable Blades, Burs, Bits and Taps

Classification Name: 87HWE Powered Surgical Instruments & Accessories/Attachments.
Common/Usual Name: Disposable Surgical Blades, Burs, Bits and Taps
Proprietary Name: Reprocessed Used, Disposable Blades, Burs, Bits and Taps
Establishment registration number: 1649663
Device Classifications: Class I per 21 CFR 878.482 - Powered Surgical Instruments & Accessories.

AMI intends to market used disposable surgical blades, burs, bits and taps that have been reprocessed. Reprocessing blades, burs, bits and taps is performed by AMI to AMI protocol Number 40014. "Reprocessed," means all operations performed to render a contaminated single-use device patient ready (*Enforcement Priorities for Single-Use Devices Reprocessed by Third Party Reprocessors and Hospitals*).

AMI is a "third party reprocessor" and reprocesses used single-used medical devices.

Used blades, burs, bits and taps that do not meet the AMI protocol are rejected. Rejection may occur during the first reprocessing (in which the item is not reprocessed at all) or anytime during subsequent reprocessings.

AMI believes that used single-use blades, burs, bits and taps can be considered "reusable" as defined in the Food and Drug Administration Compliance Policy Guide #7124: they are able to withstand the necessary cleaning and sterilization process, the physical characteristics or quality of the device will not be adversely effected, and the device remains safe and effective for its intended use.

Blades, burs, bits and taps are metal accessories and attachments used with powered surgical tools for re-constructive and traumatic bone surgery.

AMI reprocessed blades, burs, bits and taps are composed of the same materials as currently marketed blades, burs, bits and taps sold new.

Only blades, burs, bits and taps that are currently sold on the market (which have met premarket requirements by the original manufacturer for single use) are reprocessed by Adven Medical, Inc.

Predicate Devices AMI reprocessed, used disposable blades, burs, bits and taps are substantially equivalent to disposable blades, burs, bits and taps marketed new by numerous companies such as Stryker, Microair, Synthes and Komet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2002

Mr. Mark W. Aldana
President
Adven Medical, Inc.
1001 Slaton Highway
Lubbock, Texas 79404

Re: K012676
Trade Name: Reprocessed Used, Disposable Blades, Burs, Bits, and Taps
Regulation Number: 878.4820
Regulation Name: Surgical instrument motors, accessories/attachments
Regulatory Class: I
Product Code: HWE
Dated: December 3, 2001
Received: December 5, 2001

Dear Mr. Aldana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, (Misbranding by reference to premarket notification((21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510)k) Number: K012676

Device Name: Reprocessed Used, Disposable Blades, Burrs, Bits and Taps

Indications For Use:

Blades, burs, bits and taps are metal accessories and attachments used with powered surgical tools for re-constructive and traumatic bone surgery.

AMI intends to reprocess all brands of used disposable surgical saw blades, burs, bits and taps. Reprocessing includes all the steps performed to make a contaminated single use device patient ready.

Only blades, burs, bits and taps that are currently sold on the market (which have met premarket requirements by the original manufacturer for single use) will be reprocessed by AMI.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012676

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)